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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,146	02/22/2007	Michael Mahoney	101896-0474	8927
21125 7590 11/26/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER WAGGLE, JR, LARRY E				
ART UNIT		PAPER NUMBER		
3775				
NOTIFICATION DATE		DELIVERY MODE		
11/26/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/579,146

Applicant(s)

MAHONEY ET AL.

Examiner

Larry E. Waggle, Jr

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-18, 20-21, 24-27, 29-34, 44-46, 48 and 63-65 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-9, 17, 20-21, 24-27, 29-33, 44-46, 48 and 63-65 is/are rejected.
- 7) ☒ Claim(s) 10-11, 14-16, 18 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "shaft," "articulatable implant holding element" and "connecting element" as required by claim 44 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The only mention of the limitations of claims 44-46 and 48 in the specification are under the "Summary." It appears that these limitations read on the embodiment of Figures 30-33. If this is indeed the case, then the following limitation-reference number combinations will be treated as such:

Articulating implant inserter (846),
Implant (848),
Sliding element (878a and 878b),
Distal impaction face (879), and
Proximal handle (883).

Therefore, the "shaft," "articulatable implant holding element" and "connecting element" require assigned reference numbers in the "Detailed Description of the Exemplary Embodiments."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

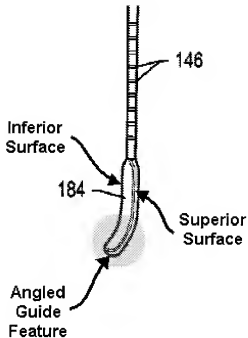
only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, 17 and 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by McKinley et al. (US Patent 6,368,325).

McKinley et al. disclose a surgical instrument system (Figure 1) comprising a distractor (20) including a shaft and a paddle (22 or 24) located on a distal end of the shaft; and a filler bar (i.e. fills the space between 22 and 24 and subsequently fills the space between adjacent vertebrae 50 and 52), including an elongate shaft (30) having a diameter less than a diameter of the distractor and a stabilizing plate (10) nested within the distractor paddle, removably and slidably engaged substantially along one side (i.e. along 26 and bore (not shown)) of the shaft and the paddle (column 5, lines 56-59) capable of providing rigidity and torque strength to the distractor as it is rotated to distract adjacent vertebrae (50 and 52; Figures 8-10). The distractor paddle includes a first height (29) when presented in an insertion orientation (Figure 8), a second height (27) greater than the first height when rotated to a distraction orientation (Figure 10) and inferior (i.e. coplanar with 13) and superior (i.e. coplanar with 15) surfaces contacting adjacent vertebrae. The filler bar is dimensioned to not extend beyond the inferior and superior surfaces of the paddle (Figures 1-3, 6 and 8-11B and column 5, line 45—column 7, line 20). Further, the system comprises a minimally invasive access port (i.e. cannula) through which the distractor is placed (column 2, lines 29-34).

Claims 20-21, 27 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb (US Publication 2005/0027360).

Webb discloses a surgical instrument system (Figures 13A-13D) comprising an instrument (182) capable of maintaining a distraction between vertebrae including a shaft (186) and a paddle (184) having inferior and superior surfaces (see annotated Figure below) located on a distal end of the shaft; an implant inserter (210; i.e. inserts the implant into final position as shown in Figure 13D) having a distal end (i.e. tip 212); and an access port (paragraph 0081), wherein the paddle and shaft present a guide surface (i.e. left surface of 184 as shown in Figure 10) and a guide feature (i.e. left surface of 186 as shown in Figure 10) for guiding the placement of the implant and interaction with the distal end of the inserter and an angled guide feature (see annotated Figure below) integral with the distal portion of the paddle to guide an implant (100) through a partial rotation to a desired angle and the paddle includes a first height (i.e. width of left surface of 184 as shown in Figure 10) and a second height (i.e. thickness of 184 as shown in Figure 13A) greater than the first height (Figures 10-13D and paragraphs 0072-0090). Further, the implant inserter includes a corresponding feature (i.e. right portion of 212 as shown in Figure 13C) capable of mating with the guide surface.



With regard to the statements of intended use and other functional statements, such as “for” and “configured to,” they do not impose any structural limitations on the claims distinguishable over Webb which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 44-46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Lim (US Publication 2004/0153065).

Lim discloses a surgical instrument system (Figure 10) comprising an articulating implant inserter (80) including a shaft (82) and an articulatable implant holding element (55 in conjunction with the distal end of 84) located on a distal end of the shaft operable from a proximal portion of the shaft to releasably hold (i.e. via 90) an implant (10), wherein the implant has a connecting element (93) external to the implant and a connecting element (i.e. portion of 30 allowing for extension of 84 to contact 40; best seen in Figures 3, 7 and 19) that cooperates with the holding element to allow articulation of the implant to a desired angle, and the holding element includes two sliding elements (81 and 84) having distal implant impaction faces contacting the implant (i.e. the exterior face of 55 connected to 81 contacts the implant on an interior surface of 93 and the exterior surface of the distal end of 84 contacts the implant at 40) operable from a proximal handle (130) to provide the articulation of the implant to the desired angle (Figures 10-16 and paragraphs 0035-0062).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinley et al. (US Patent 6,368,325).

In the embodiment of Figure 11A, McKinley et al. disclose the claimed invention except for at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulders) to prevent the migration of the distractor during distraction. McKinley et al. disclose the filler stabilizing plate (10) having protrusions / teeth / expansion shoulders (11) (Figure 11B and column 7, line 12-14). It would have been obvious to a person having ordinary skill in the art at the time of the invention to construct the invention of McKinley et al. with at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) in order to firmly anchor the distractor between adjacent vertebrae.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Frey et al. (US Publication 2002/0165550).

Webb discloses the claimed invention except for the angled guide feature being formed from a shape memory material. Frey et al. teach an inner shaft (226) of an instrument (220) being formed from nitinol (Figure 11 and paragraph 0104). It would

have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the angled guide feature being formed from nitinol in view of Frey et al. in order to provide a flexible feature for ease of manipulation when guiding through the access port and the intervertebral space.

Claims 25 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360).

Webb discloses the claimed invention except for the distal end of the inserter being angled to correspond with the angle of the angled guide feature. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the distal end of the inserter being angled to correspond with the angle of the angled guide feature in order to provide mating guide surfaces between the distractor and the inserter to reduce the overall profile of the combination, since the applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an angled distal end. In re Dailey and Eilers, 149 USPQ 47 (1966).

Webb discloses the claimed invention except for at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) to prevent the migration of the distractor during distraction. Webb discloses the implant (100) having protrusions / teeth / expansion shoulders (130) (Figure 3 and paragraph 0044). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with at

least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) in order to penetrate the vertebral plate to inhibit the removal of the distractor during distraction.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Lim (US Publication 2004/0153065).

Webb discloses the claimed invention except for the inserter having an articulating implant holder. Lim discloses an inserter (9) having an articulatable implant holding element (55) (Figures 11 and 12 and paragraphs 0035-0061). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the inserter having an articulatable implant holding element in order to precisely place the implant between vertebrae at a desired angle.

Allowable Subject Matter

Claims 10-11, 14-16, 18 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 5-11, 14-18, 20-21, 24-27, 29-34, 44-46, 48 and 63-65 have been considered but are moot in view of the new ground(s) of rejection.

In regards to the applicant's arguments with respect to the prior art used in the rejection mailed 19 March 2010, the examiner notes that these arguments are addressed by the new grounds of rejection as set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is (571)270-7110. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. E. W./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775